ALPHARMA
U.S. Pharmaceuticals Division

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Dockets Management Branch
(HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 00N-0086
Proposed Rule to Amend Regulations of Certain Label Statements on Prescription Drugs

This letter responds to the April 21, 2000 Federal Register Proposed Rule to require the labels of prescription drugs to bear the statement "Rx only" instead of "Caution: Federal law prohibits dispensing without prescription".

Alpharma USPD concurs that the statement simplifies prescription drug labeling requirements. However, as there are no safety or health concerns, we object to the Proposed Rule as written.

Limiting the format of the statement to "Rx only" or "℞ only" in liteface type unnecessarily restricts the style and format of the statement. In fact, it conflicts with the requirement of Section 502 (c) of the Act and 21 CFR 201.15 that required labeling elements be prominent and conspicuous.

Alpharma USPD initiated the revision to its entire prescription drug product labeling (approximately 200 SKUs) to incorporate "Rx only" shortly after the publication of the Food and Drug Administration Modernization Act of 1997. The guidance for industry entitled "Implementation of Section 126 of the Food and Drug Administration Modernization Act of 1997 - Elimination of Certain Labeling Requirements", revised July 1998, was referenced for format and placement of the statement.

Adhering to the guidelines provided in Section IV – Frequently Asked Questions, and exercising discretion where permitted, Alpharma adopted "℞ **Only**" (i.e., boldface, initial cap O) as the preferred format for the required prescription statement on our house label. Various other formats, acceptable according to the guidance, were used in customer-labeled product.

It is particularly noteworthy that the Guidance allowed latitude in the format of the statement, provided that the statement is prominent and conspicuous. "Rx only", in the format as it appears in the Proposed Rule (not bolded and all lower case

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letters), is the least prominent and conspicuous of all possible variations previously acceptable according to the guidance.

We also bring to your attention the first footnote in the Proposed Rule ("The Rx symbol appears in bold in this document because of type-setting limitations, however, it should not be bolded when used on the product's label."); it specifically prohibits the use of boldface type. We suggest that the footnote be modified, as follows: "The Rx symbol appears in bold in this document because of type-setting limitations, however, it is not required to appear in bold-face type when used on the product's label."

We ask that the Agency revise the statement as it appears in the Proposed Rule to allow for variations in type style and density (e.g., Rx Only, Rx only, Rx ONLY, ℞ only, ℞ Only, ℞ ONLY, etc). Printing the statement in boldface type and the use of capital letters affords it greater prominence and conspicuousness.

We trust that these comments are helpful to the Agency in finalizing the regulations.

Yours truly,

Paisley Hall

Paisley Hall
Manager, Labeling

cc: Arden Stoermer
VP Quality Affairs

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